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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,594	11/28/2005	Marc Blondel	0070663-000002	1460

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BUCHANAN, INGERSOLL & ROONEY PC  
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EXAMINER
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HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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01/22/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,594	<b>Applicant(s)</b> BLONDEL ET AL.	
	<b>Examiner</b> SUSAN HANLEY	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 11-15 and 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/08/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-8 and 11-21 are pending.

#### ***Election/Restrictions***

Claims 1-8, 11-15 and 18-21 stand withdrawn.

Claims 16 and 17 are under examination.

The remarks and amendment filed 10/8/2009 are acknowledged. The rejections not explicitly restated below are withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied in the instant application.

#### ***Drawings***

The drawings are objected to because Figures 4 and 8 have French words in them. The entire disclosure must be in English. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not

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accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Double Patenting***

Claim 16 stands provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 19 of copending Application No. 11/483,822.

Applicants did not respond to the rejection so it stands for the reasons of record.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Bach (August 10, 2003; cited in the IDS filed 11/12/2008)) in light of Liu et al. (US 20030175833) or Hundley et al. (US 20030095815).

The claims are directed to a pharmaceutical composition comprising a therapeutically effective quantity of a compound of formula II and a pharmaceutically acceptable vehicle.

Bach discloses a yeast-based assay for screening of anti-prion drugs (abstract). 6-aminophenanthridine (R= NH<sub>2</sub> in Formula II), 6-amino-8-chloro-phenanthridine (R=NH<sub>2</sub>, X is chloro, p is 0 and n is 1) and 6-amino-8-(trifluoromethyl)-phenanthridine (R=NH<sub>2</sub>, X is CF<sub>3</sub>, p is 0 and n is 1), were dissolved in DMSO to a concentration of 10 mM and were evaluated in the yeast-based assay (Figure 2). Pharmaceutically acceptable vehicle and therapeutically effective quantity as used in the reference are deemed to be the amount and carrier necessary for the

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screening methodology set forth therein for this step in pharmaceutical development. the disclosed assay is a step in the development of a pharmaceutical composition. Therefore, the amount used in the disclosed vehicle is reasonably considered to be pharmaceutically acceptable in terms of vehicle and amount.

This reference is by another since the authorship of the reference differs from the inventorship of the instant application. Thibault Andrieu, Herve Galons, Dominique Dormont and Laurent Meijer are listed as authors on the reference but are not listed as inventors in the instant application.

Claim 16 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Le et al. (1996).

Le discloses the administration of 3,4-benzoquinoline (phenanthridine, see Figure 1 which meets the composition of Formula II when R is H). The compound induces drug metabolizing enzymes thus increasing the clearance of medicaments such as morphine (page 300, Table 2). The compound also has potential utility as a chemoprotective agent (abstract). The compound was dissolved in equimolar HCl and administered by the i.g. route at a dose of 75 mg/kg daily (page 298, right column, first full paragraph).

Claim 16 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cavier (1966), translation).

Cavier discloses the evaluation of compounds for antihelminthic properties. Mice infested with *S. obvelata* received orally, at one does per day, the product to be tested in solution

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or a suspension of water (page 1 of the translation, last paragraph). Water is a pharmaceutically acceptable carrier. The dose administered was 200 mg/kg per day, the therapeutically effective amount (page 2 of the translation, first paragraph). Phenanthridine was a compound tested in the disclosed pharmaceutically acceptable carrier in a therapeutically acceptable amount (page 329 of the paper, fourth entry of the Table).

### ***Double Patenting***

Claim 17 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 20 of copending Application No. 11/483,822.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 10/8/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 11/483,822 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/  
Examiner, Art Unit 1651

/Irene Marx/  
Primary Examiner  
Art Unit 1651